



BIOETHICAL LESSONS FROM THE GELSINGER

CASE:



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TRAINING

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CONFLICT OF INTEREST STANDING COMMITTEE

- “Since Dr. Wilson’s research will be directed towards a solution in which he has a financial interest in the outcome, how can Dr. Wilson assure the University that he will not be conflicted when making decisions that could have an impact on . . . the further development of his intellectual property?”
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CONFLICT OF INTEREST STANDING COMMITTEE

- “How can Dr. Wilson and the University avoid liability for any damages if a patient died from any products produced or studied at the University?”
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THREE MYTHS OF HUMAN EXPERIMENTATION

■ MYTH 1

- The Institution Can Manage Conflicts of Interest.

■ THE TRUTH

- Financial and other Interests that potentially take the focus away from protection of the subject can not be managed.

■ THE SOLUTION

- Institutions and researchers should have no financial stake in the outcome of an experiment or in the decision of the subject to participate.
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DESIGN OF THE TRIAL

- NONTHERAPEUTIC ON SUBJECTS AFFLICTED WITH DISEASE UNDER STUDY
 - EXTREME RISK AT NO BENEFIT TO THE SUBJECTS
 - APPROVED BY
 - PENN'S BIOETHICIST
 - PENN'S IRB
 - RAC
 - FDA
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THREE MYTHS OF HUMAN EXPERIMENTATION

- MYTH 2:Everybody is watching.
- THE TRUTH: Nobody is watching.
 - Currently more than 100,000 trials involving 7-8,000,000 participants.
 - At some major institutions, 4000 current trials.
 - 5000 IRBs

THE SOLUTION

Reduce the number of trials; stop trivial research; devote resources to subject protection

EXPERIMENT MUST BE ETHICALLY DESIGNED

- PRECLINICAL UNDERSTANDING OF UNIVERSE OF HARM
 - VALID SCIENCE
 - VALUABLE
 - RISKS MINIMIZED AND OUTWEIGHED BY BENEFITS
 - NONTHERAPEUTIC: SHOMEIR P'TAYIM
 - THERAPEUTIC: CLINICAL EQUIPOISE
 - ETHICAL USE OF PLACEBOS
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INFORMED CONSENT?

- “Gene Therapy”
 - No Monkey Deaths
 - No Prior Adverse Events
 - Flu for a week
 - Preclinical work complete.
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THREE MYTHS OF HUMAN EXPERIMENTATION

- MYTH 3
 - The informed consent document evidences informed consent.
 - THE TRUTH: The document neither evidences the participant is informed nor that he or she consents.
 - THE SOLUTION: Tell it like it is: an experiment; use subject advocates; have an informed discussion and decision; be aware of the therapeutic misconception.
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RESPONSIBLE PROTECTORS OF HUMAN SUBJECTS

- Investigators
 - IRB members
 - OHRP
 - FDA
 - RAC
 - Subject Advocates
 - All Of Us
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The Bell Tolls For Thee

